Orthopedic Source Inc.

800 500 0381 Office
800 500 0382 Fax

K022711

AUG 26 2002

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant's Name:	Orthopedic Source Inc. P.O. Box 307 Loomis, Ca 95650
Contact Person:	Steve Mandell
Trade Name:	Avalon Cup System
Common Name:	Metal/Polymer Acetabular Components
Classification Name:	Hip joint metal/polymer semi-constrained porous-coated uncemented prosthesis.
Proposed Regulatory Class:	Class II
Device Product Code:	LPH
Device Class:	II
Device Classification Panel:	Orthopedic 888.3358
Substantially Equivalent To:	Avalon Acetabular Cup System (K011887)

Intended Use:
Indication: for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following:

Indications:

1. Non-inflammatory degenerative joint disease including: osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia,
2. Inflammatory degenerative joint disease including rheumatoid arthritis;
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed; and, treatment of nonunion, femoral neck fractures of the proximal femur with head Involvement that are unmanageable using other techniques.

Device Description:
The Avalon cup is manufactured from Titanium 6AL 4V Eli (ASTM F136). The Avalon Cup is porous coated with commercial pure (CP) titanium sintered beads

Mailing Address
P.O. Box 307
Loomis, CA 95650

Shipping Address
5975 Horseshoe Bar Road
Loomis, CA 95650

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(ASTM F67) to promote fixation. The Avalon Cup is a low profile cup available in three versions: [No-hole], [Three hole], and a [Multi-hole]. The holes are to allow for added fixation with bone screws. The Avalon Cup's outer geometry consists of a 14° flared rim and 8 external cutouts, which are machined into the peripheral exterior of the cup.

Device Modification:
One (1) modification is made to The Avalon Cup System. The device modification presented in this "Special" 510(k) represents a modification to the outer portion of the acetabular cup with regard to its coating. The modification is a "line extension" to add a sintered beaded coated option to the already approved plasma sprayed coated devise. No changes to any other aspect of the cup are presented in this application.

The proposed device modification has been tested and meets and exceeds the requirements provided in the Draft Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement.

Bases of Substantial Equivalence:
The subject titanium sintered beaded Avalon Acetabular Cup System is identical (except for sintering process) to the previously cleared Avalon Acetabular Cup System (plasma spray) that was cleared in 2001. It has the same intended use, same dimensions, same design, and mates with the same parts and uses the same sterilization and packaging methods. The Avalon Acetabular cup system demonstrated adequate performance in design control activities

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2002

Mr. Steven L. Mandell
President
Orthopedic Source, Inc.
P.O. Box 307
Loomis, California 95650

Re: K022711
Trade/Device Name: Avalon Cup System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prothesis
Regulatory Class: Class II
Product Code: LPH
Dated: August 8, 2002
Received: August 14, 2002

Dear Mr. Mandell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022711

Device Name: Avalon Cup System

Indications For Use:

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2) Inflammatory degenerative joint disease including rheumatoid arthritis;
3) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed; and,treatment of nonunion, femoral neck fractures of the proximal femur with head involvement that are unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR § 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022711